

REMARKS

Withdrawn Claims

Claims 10-16, 18, 19, 21, 27, 28, 30, 31, 33-39 and 56-72 have been withdrawn from consideration as being drawn to a non-elected species of the invention. The Applicant has cancelled each of the withdraw claims without prejudice for possible reinstatement in a continuing application.

Specification

The specification has been objected to as failing to provide support for the recitation that the components and instrumentation with the single container are used to perform a designated spinal stabilization procedure. Specifically, the Office Action asserts that the components and instrumentation used to perform a designated spinal “stabilization procedure” is not found in the written description. The Applicant has amended independent claim 3 to replace the term “stabilization procedure” with “fusion procedure”. Support for the recitation of a fusion procedure is found, for example, in paragraphs [0017], [0042] and [0043] of the subject application. Accordingly, the objection to the specification is deemed moot, and withdrawal of the objection to the specification is respectfully requested.

Claim Amendments

Independent claim 3 has been amended to include the subject matter recited in dependent claims 5 and 6, which have now been cancelled without prejudice. Since the subject matter incorporated into independent claim 3 was present in previously pending claims 5 and 6, no new issues are raised that would require additional consideration and/or searching.

Independent claim 3 now recites, among other elements and features, spinal implant components comprising an elongate spinal plate member, a number of bone screws, an interbody fusion implant adapted for disposition within an intervertebral space, a bone growth promoting substance for disposition between first and second vertebrae to facilitate fusion, and surgical instrumentation comprising a driver configured to drive bone screws into vertebral bone, and with each of the components and instrumentation integrally contained and sealed within a single container in a sterilized condition, and with the surgical kit being self-contained to include all of

the components and instrumentation within the single container that are required to perform a designated spinal fusion procedure.

Independent claim 3 has been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0004660 to Henniges et al. in view of U.S. Patent No. 6,273,916 to Murphy, and claims 5 and 6 have been rejected as being unpatentable over Henniges in view of Murphy, and further in view of U.S. Patent Application Publication No. 2001/20185 to Ray. More specifically, the Office Action asserts that it would have been obvious to one of ordinary skill in the art to combine the kit disclosed in Murphy, which includes components/instruments to perform a vertebroplasty procedure, with the devices disclosed in Henniges and Ray, to arrive at the invention recited in independent claim 3. The Applicant respectfully traverses these rejections for at least the following reasons, and submits that independent claim 3, as amended, is patentable over the cited references.

As an initial matter, the grounds for rejection set forth in the Office Action do not make any reference whatsoever to a surgical kit including “a bone growth promoting substance” to facilitate fusion, as originally recited in claim 6 and as now recited in independent claim 3. Accordingly, the grounds set forth in the Office Action fail to establish a *prima facie* case of obviousness. If the rejection of independent claim 3 is maintained, the Applicant respectfully requests that specific grounds be set forth in an official communication to support a *prima facie* case of obviousness.

Additionally, the Office Action asserts that “one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references”. (Page 6; citations omitted). The Office Action further asserts that “the rejection is based on the combination not on individual references being piecemeal analyzed”. (Page 7). However, the Applicant notes that “[t]o establish a *prima facie* case of obviousness, . . . there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.” MPEP §2142 (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)). Additionally, “[a] prior art reference must be considered in its entirety, i.e., as a whole, including

portions that would lead away from the claimed invention.” MPEP §2141.02 (citing W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983)).

Albeit that the cited references may disclose some of the components and devices recited in independent claim 3, independent claim 3 must be considered in its entirety, and can not be rejected based on the bare premise that various components and devices are individually disclosed in multiple patent references. In the present case, the teachings of three patent references (i.e., Henniges, Murphy, and Ray) are asserted to individually disclose various elements recited in independent claim 3. However, there must be some suggestion or motivation to combine the individual teachings of these references to arrive at the claimed invention. The Applicant notes that independent claim 3 is not merely reciting a laundry list of components and devices, but is instead reciting particular components and instruments that are packaged together to provide a surgical kit that is “self-contained to include all of the components and instrumentation within [a] single container that are required to perform a designated spinal fusion procedure”.

Although Henniges discloses a spinal plate and bone fasteners, these components are not part of a kit that is “self-contained to include all of the components and instrumentation within [a] single container that are required to perform a designated spinal fusion procedure”. To the contrary, Henniges discloses that these components are individually packaged in separate containers, and are not integrally contained and sealed within a single container. Instead of providing a self-contained, all inclusive kit which includes “all of the components and instrumentation . . . required to perform a designated spinal fusion procedure” within a single, sterilized container, Henniges specifically teaches that the components and instruments are packaged separately from one another in individual containers, which is directly contrary to the inventive concept recited in independent claim 3. Additionally, Henniges fails to disclose an interbody fusion implant and a bone growth promoting substance to facilitate fusion, and therefore does not include “all of the components and instrumentation . . . required to perform a designated spinal fusion procedure”.

Furthermore, as indicated above, references must be considered as a whole, “including portions that would lead away from the claimed invention.” As set forth in the Applicant’s prior

response, Henniges discloses features for ensuring that the appropriate plate 10 and fasteners 12 are selected from product inventory for a particular surgical procedure. Specifically, Henniges discloses that various plates 10 are color coded for identification purposes to ensure selection of the appropriate plate for the surgical procedure, and that “the package containing bioabsorbable plates 10 are marked with an identification mark, not shown. The mark allows the package with the plates 10 to be identified more precisely . . . in a manner that will allow the nurse or doctor to easily read and recognize the identification mark and the corresponding mark on the package containing the plate 10.” Likewise, “color coding of the fasteners 12 will allow easy and quick identification of different fasteners 12” to ensure selection of the appropriate fasteners for the surgical procedure. (Paragraph 67). Accordingly, Henniges specifically teaches away from the inventive concept of packaging the plates and the screws in a single container to provide a self-contained surgical kit. Such teachings must be taken into consideration in order to establish a prima facie case of obviousness.

Although Murphy discloses devices and instruments that are packaged in a common container, these devices and instruments are used in association with a vertebroplasty procedure, and not with a self-contained surgical kit including all components and instrumentation that are “required to perform a designated spinal fusion procedure”. Indeed, there is no teaching or suggestion whatsoever of providing any of the spinal implant components or instrumentation recited in independent claim 3, including a spinal plate, bone screws, a driver instrument, an interbody fusion implant, and a bone growth promoting substance. Additionally, one of skill in the art would recognize and appreciate that a vertebroplasty procedure is significantly different from a spinal fusion procedure. In summary, although Murphy discloses a kit including components/instruments to perform a vertebroplasty procedure, there is no indication or suggestion of providing a self-contained surgical kit including all components and instrumentation required to perform a designated spinal fusion procedure.

Finally, although Ray discloses an interbody implant, there is no teaching or suggestion whatsoever regarding packing the spinal components recited in independent claim 3 with a screw driver instrument configured to drivingly engage bone screws into engagement with vertebral bone, nor is there any teaching or suggestion that these components and instruments are

“integrally contained and sealed within said single container . . . in a sterilized condition” to provide a self-contained surgical kit including “all of the components and instrumentation required to perform a designated spinal fusion procedure”. Indeed, Ray fails to disclose or suggest any type of screw driver instrument, or any type of packaging or container for integrally containing and sealing the components and instruments recited in independent claim 3 in a self-contained surgical kit. The Office Action also asserts that it is understood or well known that “no surgeon would risk liability and have a surgical implant to use with a patient that is not packaged”. (Page 7). The Applicant does not dispute that spinal components and instruments are typically contained within some type of packaging. However, independent claim 3 recites more than mere packaging, but instead specifically recites packaging of components and instruments within a single container to provide a self-contained surgical kit.

In summary, the Applicant submits that independent claim 3 does not merely recite a laundry list of components and instruments, but instead recites particular components and instruments that required to perform a designated spinal fusion procedure to provide a self-contained surgical kit. As indicated above, none of the cited references disclose or suggest this inventive concept.

For at least these reasons, the Applicant respectfully requests withdrawal of the rejection of independent claim 3. Claims 7-9, 17, 20 and 22-26 depend from independent claim 3, and are submitted to be patentable for at least the reasons set forth above with regard to the patentability of independent claim 3. Accordingly, the Applicant requests allowance of independent claim 3 and the claims depending therefrom.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the Applicant's application is now in condition for allowance with pending claims 3, 7-9, 17, 20 and 22-26.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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